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## REPLY TO DES MOINES OFFICE

March 6, 2006

MAIL STOP 16  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: Refund Request re US Patent Application No. 10/037,881  
Our File No.: 4532670/6200 (KEM 42)  
Title: Bacterial Isolates From Organisms That Respire At Least Partially  
Through Their Skin And Biologically Active Extracts Derived  
Therefrom

Dear Sir or Madam:

We are requesting a refund check in the amount of \$1,020.00 that was erroneously assessed against Deposit Account No. 12-2250 in the above-identified application.

On or about February 10, 2006, the named inventor, Dr. Austin, filed (after the six-month deadline) a pro se response to the outstanding Office Action. Dr. Austin is not my client. Dr. Austin had previously been notified under a written agreement that my client, a sponsor of his research, would not be further pursuing the application and that he was free to do so on his own. The papers filed by Dr. Austin (attached) clearly indicated that he is acting on his own and independent of myself and my client Kemin Industries, Inc.

As such, Dr. Austin had no authority to use my deposit account for the payment of extension fees and I request that the amount of \$1,020.00 be replaced into Deposit Account 12-2250.

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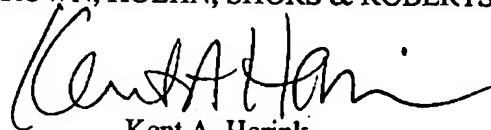
March 6, 2006

Page 2

If you should have any questions or comments regarding this matter, please do not hesitate to contact me.

Sincerely yours,

DAVIS, BROWN, KOEHN, SHORS & ROBERTS, P.C.



Kent A. Herink

KAH:jv  
Enclosure

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# PIEDMONT COLLEGE



Since Eighteen Hundred and Ninety-Seven

AF  
JRW

Richard M. Austin, Jr.

10 February 2006

Jean C. Witz  
Patent Examiner, Art Unit 1651  
U. S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

RE: Application Number: 10/037,881 ✓  
File Date: 01/04/2002  
First Named Inventor: Richard M. Austin, Jr.  
Attorney Docket Number: 4532670/6200 (KEM 42)  
Confirmation Number: 4794

Dear Mrs. Witz,

My name is Richard M. Austin, Jr., and I am the primary inventor of the material contained in this patent. I am a full-time teaching professor at a small, liberal arts college in northeast Georgia. I have been here for my entire professional career.

A company, Kemin Industries, heard of my research several years ago and approached me regarding a partnership to explore the commercial applications of my research. We entered into said partnership and pursued that goal. As a part of that goal, we pursued this patent along with multiple world patents as well. Having no prior experience with the cooperative world or patent law, I allowed their attorney to represent and direct these efforts. I questioned repeatedly why certain information was withheld from our patent application over the past years. I now believe it was because they intend to pursue related patents in the future on their own. (see addendum).

I have no prior experience in the protocol of filing a response to your objections to the claims listed in this patent. However, if it would be appropriate, I would like to respond to the arguments for the rejection of claims 1-19 in the patent application entitled "*Bacterial isolates from organisms that respire at least partially through their skin and biologically active extracts derived therefrom.*" I would also like to supply related documentation that provides proof that some of the information that you have stated

needed to be included does exist. I am still at a loss as to why Kemin failed to include such information long ago.

*Response to Objections to Claims*

1. As the primary inventor and author of the patent, I made every attempt to meet the spirit of the first paragraph of 35 U.S.C. 112. It was written in such a way as to ensure that those skilled in the art would be able to replicate the findings of my research. The methodology described in the protocols of the patent is standardized as to the search for such bacteria that possess the ability to produce antimicrobial compounds. Madigan et al. state "The classical procedure for testing new microbial isolates for antibiotic production is the cross streak method, first used by Fleming in his pioneering studies on penicillin." (Brock Biology of Microorganisms, 2003. 10<sup>th</sup> edition, page 974) (see addendum). This streak method on newly isolated bacteria, regardless of the source, is well known and what I attempted to describe in the patent.
2. I in no way refute that the existence of microorganisms on and in organisms is certainly well known. My research focuses upon amphibians as the source of medically significant bacteria. Perhaps the title of the patent should have been more narrow, a suggestion that I made to the patent attorney. Never-the-less, I never intended to indicate that all bacterial isolates would possess the ability to produce antimicrobial compounds. Most simply won't. But I have effectively demonstrated that some will. Further, I never intended to imply through the title of the patent that specific compounds would be structurally illucidated. Again, the claims were written broadly to ensure that biologically active molecules extracted from source bacteria would be covered under the patent. I am providing an unpublished white paper that was written which describes the structure and antimicrobial activity of a new class of cyclic undecapeptides produced by a bacterium isolated from the skin of an amphibian. This paper describes the structure in intricate detail and, in my opinion, should have been included in our initial patent materials or in our first response to your rejection (see addendum). Additionally, I am including a copy of an email that indicates the molecular weight and chemical formula of another compound that was isolated from an extract produced by a bacterium which was isolated from the skin of an amphibian (see addendum).
3. I am also enclosing data for the 16S rRNA gene sequence analysis for five of the bacteria isolated from amphibians that exhibited the ability to inhibit known human pathogenic bacterial species (see addendum). This research was completed in February, 2003 and should have been made available to you. As you examine this information, please note that this type of analysis compares the 16S rRNA gene sequence to known bacterial species and gives a percent match. None of my research isolates gave a 100% match, indicating that there are at least strain differences between my isolates and the data bank to which they were compared. This data would give others the ability to compare their results to determine if their isolates were the same as mine. As to allowing access for others to my bacterial library, I would make them available to anyone who requested them.

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That being said, I am simply not in the financial position to deposit my bacterial isolates in the ATCC depository bank. To do so would cost many thousands of dollars. Kemin knew this and also knew that by not providing the funds necessary to deposit said bacteria in ATCC would likely provide a major stumbling block to the perfection of this patent. As I stated earlier, I am an associate professor of biology at a small college in Georgia who makes barely enough to raise my family on. I am no longer in any partnership with any company. To require this as part of the patent requirements would be discriminatory. Please reconsider this part of your argument.

This patent application represents years of my personal research. It also successfully represents that amphibians are a novel source of bacteria that are capable of producing novel compounds that could be medically useful. Further, I have demonstrated that they are capable of inhibiting growth in bacteria, viruses and tumor cell lines.

As the world feverishly searches for answers for antibiotic-resistant bacterial infections, impending flu pandemics and never-ending sieges by cancer, this research, provides a more than plausible or possible answer for our world's needs. I have compounds isolated from bacteria found on amphibian skin that have shown great promise against diseases such as MRSA, VRE, and HIV to name a few. If this patent is ultimately rejected, my research ends...there isn't any more funding left and the world may never know what might have been available. It will also likely allow a major cooperation to bury this research so that they might use it for their own benefit in the future without having to give a portion of proceeds to someone else.

I am respectfully requesting that you please view this information included in this response as reconsider your earlier objections. If you see it in your heart to allow at least some of the claims, then I'll be able to pursue more funding. Better yet, I might be able to hand this off to a company that has the resources to work in a much more efficient and rapid manner than I could ever do as a full-time teaching professor. This isn't about money for me. This is about solving world problems through science. Please reconsider your objections to the claims. The world might hang in the balance...and yes, I believe in it that much. I just should have taken control of the responses to the patent earlier instead of letting a corporate-world attorney and major company handle it.

Please send all further communications to me personally. If I need to fill out any necessary paperwork, please send it as well. My address is as follows:

Dr. Rick Austin  
Associate Professor of Biology  
Piedmont College  
165 Central Avenue  
Demorest, GA 30535

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I appreciate any and all reconsideration you can give in this matter. Please feel free to contact me should you have any questions at all.

Best Regards,

A handwritten signature in black ink, appearing to read "Rick Austin, Ph.D."

Dr. Rick M. Austin  
(706) 778-3000 ext 1167

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**Kemin Industries, Inc.**  
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**Our Vision:**  
We strive to improve the  
quality of life by touching  
half the people of the  
world every day with our  
products and services.

February 7, 2006

Dr. Rick Austin  
Plethodon Research LLC  
1590 Double Springs Road  
Demorest, Georgia 30535

Received  
Feb 10, 2006

RE: "Bacterial isolates from organisms that respire at least partially through their skin and biologically active extracts derived therefrom" (KEM 42)

Dear Dr. Austin:

As you know, Kemin Industries and Plethodon have terminated their joint research activities. We believe that the only action required of Kemin Industries is to return to Plethodon any biological materials it has received from Plethodon. We will gather these materials and await your instructions with regard either to destruction of the materials or the address to which you would like them delivered. Destruction of the materials makes the most sense to us since you have your own cultures of these materials. We would be happy to provide you with a letter certifying destruction of the cultures when that has occurred.

As a matter of courtesy, we remind you of the approaching deadline of February 11, 2006 for responding to the August 11, 2005, Office Action on the pending US patent application, referenced above. Given the termination of the relationship, you may elect to proceed with prosecution of the patent application independently. I am sure that Kent Herink would work with you or alternative legal counsel if there are any questions.

If you have any questions, please do not hesitate to contact me directly either by telephone at 515/559-5347 or by e-mail at [libby.nelson@kemin.com](mailto:libby.nelson@kemin.com).

Regards,  
KEMIN INDUSTRIES, INC.

*Elizabeth A. Nelson*

Elizabeth A. Nelson  
Corporate Counsel

cc: Benedikt Sas  
Kent Herink  
Andrew G. Yersin, Ph.D.

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